

with block grants and vouchers, may well prove to be the best way to cover kids who need health insurance, but we all know about the unintended consequences of social policy initiatives and we all know how hard it is to reform an entitlement, even if it has truly perverse effects, and so I am proposing a 5-year demonstration of this approach in the appropriately humble spirit of "trial and correction" which I have many times before said on this floor should inform our entire project of health reform.

By making this program subject to appropriations, we ensure that we undertake this important effort in a fiscally responsible manner.

Specifically, to provide sufficient funds to properly test this approach to children's health coverage in a way that does not bust the budget, my bill establishes the "Healthy Kids Trust Fund," on budget, funded through the sale of available broadcast and non-broadcast spectrum assets. I am not wedded to this offset but offer it to make clear my intention to see this program paid for with hard dollars, not confederate money.

Furthermore, my proposal provides that:

The first year of the program, fiscal year 1998, would be devoted to HHS and State planning, with the new insurance coverage commencing on or about October 1, 1998.

Coverage would be phased in, beginning with children 0-5 years old in fiscal year 1999 and expanding in subsequent years to cover children 6-9, 10-12, and 13-17.

In the 104th Congress, I was pleased to cosponsor the Health Insurance Portability and Accountability Act of 1996, better known as the Kassebaum-Kennedy bill (S. 1028). There is no question that Kassebaum-Kennedy made significant steps forward in addressing troubling issues in health care. The bill's incremental approach to health care reform is what allowed it to generate consensus support in the Senate; we knew that it did not address every single problem in the health care delivery system, but it would make life better for millions of American men, women, and children.

In retrospect, I urge my colleagues to note a most important fact—the Kassebaum-Kennedy bill was enacted only after some Democrats abandoned their hopes for passing a nationalized, big government health care scheme, and some Republicans abandoned their position that access to health care is really not a major problem in the United States demanding Federal action.

Although we succeeded in enacting incremental insurance market reforms, there is still much we need to do to improve our health care system. Additional reforms must be enacted if we are serious about our commitment to meet the needs of the American people. I am hopeful that my colleagues understand how important it is to our constituents that we continue to reform

the health care system. Just look at the Brandt children and multiply their need by millions. Looking back at our success with the Kassebaum-Kennedy bill, I am equally hopeful that my colleagues have come to realize that if we are to continue to be successful in meeting our constituents' needs, the solutions to our Nation's health care problems must come from the political center, not from the extremes.

Mr. President, I hope the legislation I am introducing today can be the basis for taking this next, crucial step in our process of bipartisan, incremental health reform. My proposal seeks to achieve incremental expansion of health care through a conservative means—a fully funded program with carefully crafted eligibility rules for a limited period of time, a program based on State administration and personal choice and responsibility. Let us take this step. Let us make this test. Let us see to it that the anguish and Russian roulette endured by all those situated similarly to the Brandt family are stopped and millions more of our Nation's greatest assets are given a basic ingredient for decent and productive lives.

Mr. President, how much time do I have remaining on the additional time which I sought independent of Senator DOMENICI's time?

The PRESIDING OFFICER. The Senator has 7 minutes and 10 seconds remaining. The Senator from New Mexico has 39 minutes remaining in regard to the previous order.

Mr. SPECTER. I thank the Chair.

MAMMOGRAMS

Mr. SPECTER. Mr. President, the final subject I wish to address briefly involves the problem of mammograms for women age 40 to 49.

Mr. President, this subject came into sharp focus when a National Institutes of Health panel on January 23 issued a report that mammograms were not warranted for women in the 40 to 49 category. That was immediately met with very widespread criticism, including criticism from Dr. Richard Klausner, the Director of the National Cancer Institute, who said that he was shocked by that conclusion. As the facts later developed, a press release was inadvertently disclosed. Some of the members of the panel had held that mammograms were not warranted. But, as I understand it, that had not been thoroughly analyzed and agreed upon by the panel. But once this press release came out they stood by the release. And there has been enormous confusion in America on this issue of women 40 to 49.

The subcommittee, which I chair and which has jurisdiction over the Department of Health and Human Services, had a hearing on February 5 at which Dr. Klausner restated his shock about the matter. He thought that the advantages of mammograms for women 40 to 49 had not been appropriately empha-

sized, and the disadvantages had been emphasized too heavily. He also said that he was going to await a meeting of the National Cancer Institute later in February—on February 24 and 25. It was my understanding that the matter would be resolved at that time. But, in fact, it was not.

When the Secretary of Health and Human Services testified before our subcommittee on March 4 she said that there would be a 2-month delay, which I said in those hearings was unacceptable. I have since pressed Dr. Klausner as to why there would be such a delay.

I wrote to him on March 5, 1997. I ask unanimous consent that the text of that letter be printed in the RECORD following my statement.

The PRESIDING OFFICER. Without objection, it is so ordered.

(See exhibit 1.)

Mr. SPECTER. Mr. President, when I was dissatisfied with his response, I wrote to Dr. Harold Varmus, Director of the National Institutes of Health, the overall supervisor, on March 6, 1997 asking that there be some acceleration of this determination because no further tests were necessary but only a judgment was needed. What I found was that the matter was being referred to a 7-person subcommittee which was going to deliberate on the issue and then take it up by an 18-person full committee.

I ask unanimous consent that my letter to Dr. Varmus and a subsequent letter to Dr. Klausner be included in the RECORD following my statement.

The PRESIDING OFFICER. Without objection, it is so ordered.

(See exhibit 2.)

Mr. SPECTER. I am concerned that the delays in mammograms could constitute a health hazard for women 40 to 49. And, beyond that, that there is much confusion in America on that subject. The upshot of it has been that there now appears that the subcommittee will render its report to the full committee on this Friday, and there will be a final report rendered next Tuesday which will eliminate the need for accelerated hearings in our subcommittee to try to come to a conclusion on this important matter.

I emphasize that I appreciate the need for an independent medical judgment on this important subject.

It seems to me that where all the tests have been performed and it is a matter of issuing guidelines, coming to closure and judgment on this should not require such a lengthy period of time. I believe that there is not a sufficient sense of urgency generally, and in Government specifically, as this issue has been addressed. My views are expressed more fully in these letters, and I shall not take a greater period of time to elaborate upon them here.

In coming to my own judgment that mammograms are warranted for women 40 to 49, the subcommittee held hearings in Pittsburgh, in Hershey, and in Philadelphia, where we heard from a long array of witnesses. A report has

been prepared by my able staff member, Betty Lou Taylor, and also by Craig Higgins. I ask unanimous consent that this statement be printed in the RECORD following my oral statement. It sets forth the findings of prominent doctors in Pennsylvania and quite a number of women in the 40-to-49 category who give firsthand testimony about the importance of mammograms for them and the importance of mammograms generally for women in the 40-to-49 category.

The PRESIDING OFFICER. Without objection, it is so ordered.

(See exhibit 3.)

Mr. SPECTER. It is my hope, Mr. President, that we will have a definitive statement, as I say, next Tuesday. We need the definitive statement so that we come to closure on the issue, and then it is a matter for scientists acting on their independent judgment. It is my hope and expectation that the abundance of scientific tests which are already available will show that mammograms are important for women 40 to 49.

When I talk about medical tests, I speak from some personal experience, having had an MRI which disclosed a very serious problem. On these medical examinations, the earlier the better, so I hope we move ahead as promptly as we can.

I thank the Chair and yield the floor.

EXHIBIT 1

U.S. SENATE,
COMMITTEE ON APPROPRIATIONS,
Washington, DC, March 5, 1997.

RICHARD D. KLAUSNER, M.D.,
Director, National Cancer Institute, Bethesda, MD.

DEAR DOCTOR KLAUSNER: I was very distressed to hear Secretary Shalala's testimony yesterday that there will be another two-month delay on having the National Cancer Institute reach a conclusion on whether mammograms are warranted for women aged 40 to 49.

As disclosed in our previous hearing, the NIH consensus development conference panel press statement of January 23, 1997, was probably inadvertently released. That resulted in a lot of anxiety for women in the 40 to 49 age category and beyond. When you testified before the Subcommittee on February 5, 1997, the expectation was that the matter would be resolved by further NCI proceedings on February 25, 1997. Now we hear that there will not be a definitive statement until early May.

During the intervening 60 days, thousands of women in the 40 to 49 age category might be screened which could result in the saving of many lives.

I would appreciate your immediate response as to why the National Cancer Institute cannot make a prompt decision, or in the alternative, give our Subcommittee an earlier date.

Sincerely,

ARLEN SPECTER.

EXHIBIT 2

U.S. SENATE,
COMMITTEE ON APPROPRIATIONS,
Washington, DC, March 6, 1997.

Dr. HAROLD VARMUS,
Director, National Institutes of Health, Bethesda, MD.

DEAR DOCTOR VARMUS: With this letter, I am sending you a copy of a letter I sent to Dr. Klausner yesterday.

Earlier today Dr. Klausner and I had a conversation which I considered totally unsatisfactory. Dr. Klausner had set a time limit of 60 days for the subcommittee to report back to him; and when I said I thought that was unreasonably long, he said they would do it as soon as possible. When I asked him how long that would be, he said he didn't know and referred me to Dr. Barbara Rimer.

When my Chief of Staff, Craig Snyder, called Dr. Rimer, she advised that 60 days was the outside period with the hope that her subcommittee could act more promptly. Dr. Rimer then outlined a procedure where she had drafted a proposed statement for her subcommittee of 7 members which was circulated today with the response time a week from today. After that, Dr. Rimer expected to have a conference call among 18 members of the full committee to resolve the issue with the hope that all of that could be concluded within 10 days.

In my opinion, this is an extraordinarily unwieldy procedure and judgments could really be made at the National Cancer Institute since no additional research is necessary.

If the procedure outlined by Dr. Rimer is followed, I urge you to escalate the pace by having the comments of the 7 subcommittee members returnable next Monday with the conference call of the full 18 members of the National Cancer Advisory Board to be completed promptly thereafter so that the final comments can be completed by the end of next week.

Again, in my opinion, the Department of Health and Human Services, NIH and NCI do not have an appropriate sense of urgency on this matter. I do not have to tell you how many lives could be saved with prompt screening of women 40 to 49 without the kind of delay occasioned since the first release of January 23.

I would appreciate your immediate response on this matter.

Sincerely,

ARLEN SPECTER.

U.S. SENATE,
COMMITTEE ON APPROPRIATIONS,
Washington, DC, March 11, 1997.

RICHARD D. KLAUSNER, M.D.,
Director, National Cancer Institute, Bethesda, MD.

DEAR DOCTOR KLAUSNER: I had asked my staff yesterday to set the hearing for the National Institutes of Health including the National Cancer Institute for March 18 because of my concern about the prospective 60-day delay on the issue of mammograms for women 40 to 49.

When I heard you were going to be out of the country from March 14 to March 21, I sought to schedule the hearing for this week, on March 13, because the Senate will be out of session from March 24 through April 6 and I did not want to wait so long on this mammogram issue.

I have since been advised that the NIH subcommittee will circulate its decision to the full committee this Friday and the full NIH committee will act on March 18. While I really believe there has been too much delay up to now on the resolution of this issue, at this point I suppose that's about as expeditious a decision as can be made.

As I think you understand, my point all along has been that the matter ought to be resolved one way or another. I appreciate and understand the importance of independent medical judgment but the time delays for the NIH subcommittee and full committee frankly puzzle me. When you had expressed your own "shock" on the NIH panel finding back on January 23, and the bulk of the evidence supports mammograms for women 40 to 49, I had thought the matter to

be pretty much resolved since there were no further tests to be conducted but only a judgment to be made. It was my thinking that 60 more days from the testimony of Secretary Shalala on March 4 was unacceptable.

In any event we will await the final guidelines on March 18 and we will defer the NIH/NCI hearing until April at which time we will take up the procedures which you have employed on the issue as well as the other substantive matters affecting the National Institutes of Health including the National Cancer Institute.

Sincerely,

ARLEN SPECTER.

EXHIBIT 3

Mr. President, in recent weeks, I have been holding hearings here in Washington and around my home state of Pennsylvania on the recommendation made on January 23, 1997 by the NIH Consensus Development Conference Concerning Breast Cancer Screening for Women Between the Ages of 40 and 49. The panel concluded, "that the available data did not warrant a single recommendation for mammography for all women in their forties." Instead, the panel reiterated the 1993 recommendations of the NCI that each woman between the ages of 40 and 49 should decide for herself whether to undergo mammography.

On January 23, 1997 after the press release was issued by the Consensus Panel, Dr. Richard Klausner stated that his own reading of the studies and information presented to the conference, in contrast to past years, was that we now have available more convincing evidence. The evidence is primarily from Swedish population screening studies that there is a statistically significant benefit in terms of reduced death from breast cancer for women who begin screening in their forties. Women in that age group who decide to begin screening should be aware of the increased evidence of benefit and of any potential risk. A woman's decision to be screened or not screened should be made on the basis of knowledge.

Breast cancer is the second leading cause of cancer death in American women and according to the American Cancer Society, nearly 44,000 women will die from the disease this year, and 10,000 of these women will be in their forties, making breast cancer the number one cause of death in this age group. It seems to me that those numbers alone should signal an alarm that women in this age bracket are at great risk. And while mammography is not perfect, it is the best tool currently available.

FEBRUARY 5, 1997, WASHINGTON, DC

On February 5, 1997, at a hearing here in Washington, I discussed this issue with a panel of distinguished scientists, including Dr. Richard Klausner, the Director of the National Cancer Institute, Dr. Susan J. Blumenthal, Deputy Assistant Secretary for Women's Health, Dr. David Hoel, a Member of the NIH Consensus Development Conference, Dr. Marilyn Leitch, Associate Professor of Surgery at the University of Texas Southwestern Medical School in Dallas, Texas, and Dr. Barbara Monsees, Associate Professor of Radiology and Chief of the Breast Imaging Section of the Mallinckrodt Institute of Radiology, Washington School of Medicine in St. Louis, Missouri.

Dr. Klausner expressed concern that the balance and tone of the Panel's draft report overly minimized the benefits and overly emphasized the risks for women in their 40s. Dr. Klausner also stated the National Cancer Advisory Board would discuss the screening issue at their next meeting. That meeting took place on February 25, and resulted in the formation of a special subcommittee to

develop clear recommendations to the NCI on screening mammography. Dr. Klausner told the subcommittee that the Board intends to complete the process in two months.

Dr. Blumenthal discussed the Department's efforts to improve breast cancer detection and diagnosis to ensure that today's mammography techniques are of the highest quality. She also stated that breast cancer is perhaps the most dreaded and feared disease in women and that it has become an epidemic in our country: the number of women affected by this disease has increased from 1 in 20 over a time in the 1950s to 1 in 8 today.

Dr. Blumenthal spoke of the new frontiers in breast imaging such as ultrasound, digital mammography, breast MRI and Positron Emission Tomography as ways to improve early breast cancer detection. She also described the "Missiles to Mammograms" initiative to adapt advanced defense, space, and intelligence imaging technologies from the DOD, CIA and NASA, to more accurately detect breast cancer.

Next, the Subcommittee heard testimony from David G. Hoel, Ph.D., who is Professor and Chairman of the Department of Biometry and Epidemiology at the Medical University of South Carolina. Dr. Hoel, who is a member of the NIH Consensus Panel briefly outlined the process by which the Panel reviewed available research on the subject and derived its conclusions. Dr. Hoel also detailed the specific questions the panel was charged with answering and further noted that the Panel was restricted to providing answers to specific questions. The Panel is currently involved in completing its work and stated that the Panel's final conclusions would accurately represent the consensus view of its members.

We then heard from a panel of expert witnesses representing the American Cancer Society, the Breast Cancer Foundation, and the National Breast Cancer Coalition.

Speaking on behalf of the American Cancer Society was Marilyn Leitch, M.D., who is Associate Professor of Surgery at the University of Texas Southwestern Medical School at Dallas. She reaffirmed the American Cancer Society's position that the conclusions reached by the Consensus Panel are at variance with the data presented by both European and U.S. scientists, and therefore did not offer women and their physicians the best guidance possible. She noted that the National Cancer Institute and eleven other organizations in 1989 concluded that women in their forties should have regular mammograms. That position was reaffirmed in 1992 after a subsequent review of the scientific evidence.

In 1993, however, NCI withdrew its recommendation on the grounds that randomized clinical trials had not shown a statistically significant reduction in mortality among women under age 50. Since that time, however, two Swedish studies and a statistical compilation of eight clinical studies have been released showing solid epidemiological and clinical evidence that routine screening is effective in reducing breast cancer mortality. The Swedish studies showed statistically significant reductions in mortality of 36 percent and 44 percent, respectively, for groups invited to be screened.

Dr. Leitch conveyed the American Cancer Society's disappointment that the Consensus Panel placed undue emphasis on two issues: the risk of radiation-induced cancer and the issue of false positives and false negatives. She noted that the Society currently recommends that women in their forties be screened every one to two years. Later this month, the Society will convene its own expert panel, however, to determine if, based on new evidence, the mortality benefit might be even greater if women are screened annually.

The Subcommittee then heard from Ms. Susan Braun and Ms. Diane Rowden, both representing the Susan G. Komen Breast Cancer Foundation, a nonprofit organization that supports research on breast cancer.

Ms. Braun noted that when breast cancer is found in its earliest stages, the likelihood of 5-year survival is over 95 percent, but when found after it has metastasized, that survival rate drops precipitously—to 20 percent. Clearly, early detection is a key to longevity. And while she points out that mammography is far from a perfect tool, it has proven to save lives. Ms. Braun contends that the benefits of early screening outweigh the risks, and that is why the Komen Foundation guidelines recommend screening every one to two years, beginning at age 40. Ms. Rowden reaffirmed that position. She cited data estimating that in 1996, women in their forties would account for 18.1 percent of newly diagnosed invasive breast cancers, compared with 16.8 percent for women in their fifties.

We next heard from Frances M. Visco, Esquire, the first President of the National Breast Cancer Coalition and a member of its Board of Directors. Ms. Visco told the Subcommittee that her breast cancer was diagnosed through a mammogram when she was 39 years old. She stated that we cannot act as though the issue whether to recommend screening for women age 40 to 49 is the most important question surrounding breast cancer and that our outrage should be saved for the fact that we do not know how to prevent the disease, how to cure it, how to detect it at an early stage, or what to do for a woman once we do find it.

Ms. Visco went on to ask what is the goal? A simple message that is less confusing? She stated that in this situation, the simple message is wrong. She further stated that we want mammography to work for all women. It does not. We want to reduce breast cancer to a sound byte. It cannot be. We should be devoting our resources to designing mechanisms to get the message out to women; to get them to understand the risks, the benefits, the pros, the cons, so they can make their own decision.

Ms. Visco also told the Subcommittee in her view \$590 million should be devoted at the NIH to research on breast cancer and \$150 should be spent for research purposes at the Department of Defense.

Ms. Visco concluded that women cannot continue to be given false hope. If women in their 40s are told to get a mammogram every year, we are saying ignorance is bliss. What we need to tell them is that there are pros and cons, there are risks and benefits. That is the information they need to get. Then let them decide the course of their own care.

Our last witness was Barbara Monsees, M.D., who is Chief of the Breast Imaging Section at Mallinckrodt Institute of Radiology at the Washington University School of Medicine in St. Louis. She shared her unique perspectives as both a medical professional and as a woman who survived early breast cancer detected by a mammogram.

Dr. Monsees confirmed the fact that there appears to be clear scientific evidence that early screening can substantially reduce the death rate from breast cancer. She, too, cited the findings from five major population-based screening programs in Sweden. Two of the trials showed mortality reductions of 44 percent and 35 percent, respectively, while an overview study of all five indicated a 23 percent mortality reduction.

Unfortunately, according to Dr. Monsees, the NIH Consensus Panel chose to ignore this most recent data, resulting in "an unbalanced presentation of the facts . . ." Dr. Monsees raised some provocative questions, such as "Could this issue have taxed the NIH

consensus development model beyond its intended purpose?" And "Were the panelists given adequate time, information and instruction regarding the rules of evidence in order to formulate their report?" In conclusion, she voiced hope that the National Cancer Advisory Board will re-examine all the evidence in an unbiased fashion, and conclude that screening women in their forties does save lives.

FEBRUARY 20, 1997, PHILADELPHIA, PENNSYLVANIA

On February 20th, 1997, I reconvened the Subcommittee for our hearing in Philadelphia.

I opened the hearing with a report on a promising opportunity I learned of last year, whereby certain defense imaging technology may prove useful in more accurately detecting breast cancer in its early stages. I saw to it that this project received the necessary funding, and I look forward to seeing the results.

Once again, we heard from a very distinguished group of witnesses, led off by Dina F. Caroline, M.D., Chief of the Division of Gastrointestinal Radiology and Mammography at Temple University Hospital.

Dr. Caroline began by tracing the history of mammographic screening for women in their forties, beginning in 1977, when the National Cancer Institute and the American College of Surgeons recommended it for women with first degree relatives with breast cancer. Where the controversy came to a head was in 1993, when NCI reversed its stance, stating that experts do not agree on the value of routine screening for women in their forties.

In subsequent testimony, Dr. Caroline noted the concerns of the NIH Consensus Panel with respect to false positive results. But as she points out, until technology improves, we must expect false positive readings simply because the whole purpose of screening is not to miss any opportunity to identify breast cancer. False negatives are also a problem. But with new techniques in development, hopefully these will begin to diminish in number.

In conclusion, Dr. Caroline finds the available data sufficient enough to advocate screening for women in their forties.

Our next witness was Stephen Feig, M.D., Director of Breast Imaging and Professor of Radiology at Jefferson Medical College. Like other witnesses, Dr. Feig cited the latest clinical studies which found that current mammographic techniques should be able to reduce breast cancer deaths by at least 40 percent. He went on to point out that 20 percent of all breast cancer deaths and 33 percent of all years of life expectancy lost to breast cancer are due to cancer found in women in their forties. Not to advise screening in this age group, he contends, is unconscionable.

The Subcommittee then heard from Daniel C. Sullivan, M.D., the Chief of Breast Imaging at the Hospital of the University of Pennsylvania, and a member of the NIH Consensus Panel. Dr. Sullivan was careful to point out that the Panel's statement that has raised so much controversy is only a draft version. More importantly perhaps, Dr. Sullivan advocates annual mammography for women in their forties and emphasized his hope that the Panel's final statement will reflect that position. He went on to underscore the need for more research, as well as improved access to mammography through more consistent insurance coverage.

Bonita Falkner, M.D., a Professor of Medicine and Pediatrics at the MCP Hahnemann School of Medicine at the Allegheny University of the Health Sciences and Acting Director of the Institute for Women's Health

noted in her testimony that the controversy over the scientific merit of mammography in younger women should not confuse the facts for women 50 and above. She also stated that all women in their 40s should have access to a physicians counseling on mammography, and she found it particularly troubling that the Panel's failure to endorse screening has the potential to lead to a failure on the part of insurers to pay for the procedure. Dr. Falkner stated with the increased mortality rate among minority and disadvantaged women, particular efforts must be made to provide access to physician counseling and breast screening for these women at all ages.

The Committee then heard from Robert C. Young, M.D. Dr. Young is the President of the Fox Chase Cancer Center and in his testimony, Dr. Young maintains that for women under age 40, without other risk factors, the risk of breast cancer is quite low and there is no convincing argument for mammography screening at all. Where the gray zone occurs, he notes, is in women between the ages of 40 and 50, where there is generally a lower incidence of breast cancer, difficulty in detecting the disease, and differences in the biology of the tumors themselves. Because of these complications, small or short-term studies fail to yield clear results. In order to arrive at more definitive results, larger, long-term trials are required. And as he points out, trials such as those done in Sweden have shown small but definite improvement in survival rates.

Moreover, Dr. Young made an important point in his testimony: That guidelines are just that—guidelines. And in the case of mammography screening for women in their forties, even though the benefit may be small, the risk is minuscule. He contends that ultimately the solutions will be found through research that addresses the more fundamental questions and leads to new ways to prevent or eliminate this horrible disease.

The next witness to appear before the Subcommittee was Ms. Barbara De Luca, the Executive Director of the Linda Creed Breast Cancer Foundation. Ms. De Luca highlighted the Consensus Panel's conclusion that there is no clear indication that yearly mammograms for women in their forties save lives. She contends that the Panel's conclusion was based on economic reasons, that mammograms cost money. She went on to report on a small sampling of her Foundation's members. The women she surveyed were diagnosed with breast cancer in their forties. While mammograms had failed to discover their cancer, each of those surveyed felt strongly that women in their forties, nevertheless, should be encouraged to undergo screening every year.

Ms. De Luca reported that a mammogram done seven years ago had failed to identify her breast cancer, but that since that time new modes of detection have been developed, including the MRI and digital mammography. She recommended that tools like MRI should be made more accessible and less expensive. She urged more research be directed to finding a blood test or other methods to turn off cancer cells and arrest the disease. This, coupled with early detection, can mean finding an effective cure for breast cancer.

Ms. Lu Ann Cahn, a reporter for WCAU-TV testified that her experience was similar to Ms. De Luca, in that her mammogram failed to detect the cancer. And also like Ms. De Luca, she was appalled by the Consensus Panel's failure to recommend annual mammograms for women in their forties. She noted that this year 6,000 women in their forties will die of breast cancer, while the NIH is relaying a confused message that many women will take to mean they need not worry.

In a very compelling fashion, Ms. Cahn concludes that the recommendation of the consensus panel has given every woman who wants to avoid mammograms an excuse to do so.

The Subcommittee once again heard from Ms. Frances M. Visco, Esq., the President of the National Breast Cancer Coalition and a breast cancer survivor. Ms. Visco spoke out in support of the consensus panel's findings. But more importantly she urged that we devote our resources to empowering women to understand the available information and discuss it with their physician. She issued a call to arms of sorts, urging us to focus more of our resources and energy on convincing more women in their forties to be screened and to support a greater investment in research to find a cure, effective treatment, and more accurate ways to detect breast cancer. And she called for a greater commitment to guaranteeing access to quality health care for all women and their families.

Ms. Visco once again told the Committee, as she did in Washington, DC on February 5, 1997, that the National Breast Cancer Coalition is recommending \$590 million in research dollars at the NIH and \$150 million for the Department of Defense Breast Cancer Research Program. Ms. Visco stated that these figures were based on the percentage of proposals that are scientifically valid, but are not funded because of the lack of resources.

We then heard from Barbara Mallory, M.S.N., R.N., who represented the Nurses of Pennsylvania, an advocacy group for nurses and patients. Her contention is that every health professional she knows suspects that far too much consideration was given to the financial rather than the human costs associated with mammograms.

Her organization has been very active in this field, drafting legislation ending so-called drive-through mastectomies. In her position as a nurse she has encountered many women, some as young as 33, who have had breast cancer diagnosed as a result of self-examinations and mammograms.

Ms. Mallory went on to cite statistics about Ductal Carcinoma In Situ (DCIS), where, since the mid-1980s, there has been a 200 percent increase in the number of lesions detected by mammography. About one-half of these lesions have been found in women under age 50. Up to 25 percent will lead to invasive cancers. While mammography techniques need to be improved, she argues that ambiguous messages and too much attention to the financial bottom-line do a great disservice to the women of this Country.

Our last witness for the day was Lawrence Robinson, M.D., M.P.H., the Deputy Commissioner of the Philadelphia Department of Public Health.

Dr. Robinson told of his strong support for mammography screening for women between the ages of 40-49 and stressed this particularly for African American and Hispanic women. Dr. Robinson reported on a study done at a health event sponsored by the Philadelphia Health Department, the Pennsylvania National Guard and the Fox Chase Cancer Center where a mobile mammography unit performed 43 mammograms. Many of the women screened were under 50. The screening found 6 abnormal readings or 15% of those screened. This result points out the need to do screening particularly in underserved areas.

FEBRUARY 24, 1997, PITTSBURGH, PENNSYLVANIA

The third in a series of special hearings was convened on February 24th in Pittsburgh. I opened the hearing by telling the witnesses that the more I hear about this subject, the stronger I feel that the National Cancer Institute should take whatever steps

are necessary to resolve this issue in favor of recommending regular mammograms for women in their forties.

At this hearing, we heard from two panels of distinguished witnesses, led off by Thomas S. Chang, M.D., who is Assistant Professor of Radiology at the University of Pittsburgh School of Medicine and staff radiologist at Magee-Women's Hospital.

Dr. Chang specializes in women's imaging, with a significant portion of his practice devoted to breast imaging. As an expert in this field, he reported being disappointed by the Consensus Panel's inconclusiveness on this issue, noting that the Panel did nothing to clear the confusion that now exists. While the panel may have concluded that insurers should pay for mammograms for women who want one, he is concerned that companies will interpret the Panel's overall conclusions as not requiring them to reimburse the cost of this procedure. In short, many women—especially those who are economically disadvantaged—will have their minds made up for them as a result of financial constraints.

Dr. Chang went on to report that breast cancer is far more common in women in their forties than some have implied. In 1996, in fact, there were more breast cancers diagnosed in women in their forties (33,400) than women in their fifties (30,900).

Dr. Chang is convinced that mammography saves lives and is a medically effective screening test for women in their forties. He advises his patients to have regular mammograms once a year, and encouraged the NIH to make the same recommendation.

Dr. Howard A. Zaren, Director of the Mercy Breast Center for the Pittsburgh Mercy Health Systems told the Subcommittee that in 1997, 11,000 new cases and 2,700 deaths from breast cancer will occur in Pennsylvania. These figures place Pennsylvania within the top five states for highest incidence and mortality from breast cancer. He further stated that almost 20 percent of all breast cancer deaths, and 34 percent of all years of life expectancy lost, result from cancers that are found among women younger than the age of 50 years.

Dr. Zaren also stated that epidemiologic studies show a shift towards diagnosing breast cancer at earlier stages in women 40-49, and this is regarded as indirect evidence of a possible benefit from screening these women. He also cited the statistics of Dr. Stephen A. Feig, from Thomas Jefferson University, who had testified before the Subcommittee in Pittsburgh, that a mortality reduction of up to 35 percent can be expected if annual screening mammograms are performed in the 40-49 age group with current mammographic techniques and two-views per breast.

Our next witness was Dr. Victor G. Vogel, Professor of Medicine and Epidemiology and Director of the Comprehensive Breast Cancer Program at the University of Pittsburgh Cancer Institute and Magee-Women's Hospital. Dr. Vogel told the committee that mammographic screening holds the promise of early detection of breast cancer in a curable stage. He also commented on the eight randomized studies on which the consensus panel based their recommendation. He stated that the studies show unequivocally that for women ages 50 to 59 years, mammography reduced the chance of dying from breast cancer by approximately 30 percent. However, only one study was designed specifically to investigate screening in women 40 to 49 and that study was seriously flawed. However, meta-analysis from screening studies demonstrates a 24% reduction in breast cancer mortality attributed to screening when women in their 40s are compared with women of the same age who are not screened.

Dr. Vogel also cited some very interesting statistics stating that in Pennsylvania there are nearly 1 million women between the ages of 40 and 49, and nearly 2,000 will be diagnosed with breast cancer this year. Tragically, as many as 1,000 of these women may die. In his opinion, that number could be reduced by approximately 250 deaths if women between the ages of 40 and 49 were screened annually with mammography.

Our next witnesses was D. Lawrence Wickerham, M.D. Associate Chairman and Director of Operations for the National Surgical Adjuvant Breast and Bowel Project. Dr. Wickerham stated that his greatest concern is that the consensus statement not be used by insurance carriers as a reason to deny coverage for mammograms. He further stated that he did not disagree with the consensus statement which directs women to decide for themselves whether to undergo mammography. He felt that in order to make an informed choice, women and their health care providers need to have the best possible educational materials to aid them in these decisions. He felt that there is likely to be a sliding scale of benefit for women in their 40's and that potential benefits can be assessed by a woman in consultation with her health care provider and based on her individual circumstances.

Diane F. Clayton testified she is a breast cancer survivor mainly due to early detection. The ductile carcinoma in-situ was found during a routine mammogram—she was 46 years old.

Ms. Clayton questions the NIH consensus panel's motives. Was it money driving their direction? Was it ignorance? Was it politics? Who could be against preserving extending the lives of mom, sis, Aunt Mary and grandma? Her hope was the recommendation was an honest effort that just went bad. She felt that if it was a mistake then we should admit it and go forward by doing the right thing; advice and counsel women in their forties to have routine mammograms.

The Subcommittee then heard from Ms. Judy Pottgen, a 47 year old woman who was diagnosed with breast cancer when she was 43. Ms. Pottgen found her breast cancer by self breast exam. She is passionate about educating women about self breast exam. She described a program called "check it out", a Pittsburgh program sponsored by the American Cancer Society, Hadassah, and the Allegheny County Board of Health. The program teaches junior and senior high school girls the proper way to do self breast exam.

Ms. Pottgen summed up her testimony by telling the Subcommittee that preventive medicine is a lot cheaper than therapeutic medicine and that a mammogram is a lot cheaper than major surgery followed by radiation and chemotherapy. She cited the NIH recommendation, many years ago, that yearly Pap smears were unnecessary and wondered how many women missed the opportunity to have their cervical cancer diagnosed at an early stage. She wondered if it would be the same with mammograms, and questioned how many women will lose their breasts or be disfigured or die from this dreaded disease before NIH realizes the tremendous diagnostic benefit of mammograms.

The next witness was Ms. Yvonne D. Durham, an African American breast cancer survivor who found her cancer through self breast exam. She was 46 years old. She stated that she was deeply troubled by the Consensus Panel's decision not to recommend regular mammogram screening for women beginning at age 40 and told the Subcommittee that the recommendation sends a confusing message to the public.

Ms. Durham cited statistics based on data from 1987, that African American women, age 35-44, had a breast cancer mortality rate

2 times that of white women at the same age. Yet African Americans, as well as Hispanic Americans, have some of the lowest mammogram screening rates in the United States.

Ms. Durham concluded her testimony by stating that the benefit of mammography far outweighs any risks associated with this screening test. She also urged continued support for research efforts that may offer a clearer understanding of how breast cancer disease affects minority populations.

The last witness of the day was Ms. Laurie S. Moser, the Executive Director of the Pittsburgh Susan G. Komen Breast Cancer Foundation Race for the Cure. Ms. Moser was diagnosed with ductal carcinoma in-situ in 1987 at the age of 40.

She stated that the Komen Foundation strongly disagrees with the latest decision from the NIH Consensus Development Conference on Breast Cancer Screening for Women Ages 40-49. She also told the Subcommittee that an estimated 16.5 percent of new breast cancer cases were women in their 40s. The position of the Foundation is that the Panel's position overstated potential risks and understated the benefits of mammography. The fact is that many consumers look to the opinion of a body of experts to interpret data and provide recommendations which they can weigh as they make decisions. The current Panel statement does nothing more than confuse the public about an extremely important issue.

Ms. Moser stated that when the Race for the Cure began in Pittsburgh in 1993, a woman died every 11 minutes from breast cancer. Today, a woman dies every 12 minutes. Over 2,000 additional lives are saved each year with early detection. The goal should be to add a minute each year in the hope that more and more women will survive breast cancer.

Ms. Moser concluded that she hoped Dr. Klausner and his colleagues at the cancer institute take a closer look at the conference recommendation and see to it that women are given the highest degree of encouragement to get screening earlier, rather than later.

MARCH 3, 1997, HERSHEY, PENNSYLVANIA

On March 3, I convened a hearing at the Hershey Medical Center.

The Subcommittee's first panel consisted of a distinguished group of physicians from the local medical centers. Our first witness was James F. Evans, M.D., Director, of Surgical Oncology and Assistant director of General Surgery from the Geisinger Clinic.

Dr. Evans, expressing his personal opinions, stated that he had studied the clinical trial data and if he were to write his own consensus statement, it would say that the available data specifically does not warrant a single guideline recommendation for women between the ages of 40 and 70 years, namely annual screening. However, guidelines are not recommendations for individual women. He further stated that we would all like to have enough data to make specific recommendations for each individual based on personal profiles and highly specific reliable research data. But that data does not exist. The best data we have comes from trials and that data supports a guideline recommendation for annual screening beginning at age 40. Clinicians and women themselves should then use additional but less reliable data that we have to make decisions for individuals.

Our next panelist was Mary Simmonds, M.D., Chief of the Division of Medical Oncology for Pinnacle Health Systems in Harrisburg. Dr. Simmonds stated that she supported the American Cancer Society recommendations that women in their 40s

should undergo screening mammography every one to two years.

Dr. Simmonds also shared with the Committee a copy of Recommendations for a Statewide Plan for the Early Detection of Breast Cancer formulated as a result of deliberations of a Pennsylvania Breast Cancer Awareness Consensus Conference. The recommendations from this conference were that (1) mammography saves lives; (2) women should have a mammogram even if you don't have any symptoms; (3) women should ask their doctor for information about mammography and for access to mammography (4) follow the American Cancer Society guidelines for the frequency of mammography and physical examination of the breast as well as the performance of breast self examination.

Testifying on behalf of the Hershey Medical Center was David M. Van Hook M.D., and Assistant Professor of Radiology and Chief of Mammography at the medical center. Dr. Van Hook told the Subcommittee that although an analysis of the combined data from the seven population-based randomized-controlled trials, which included over 170,000 women in their 40s, demonstrated a statistically significant benefit in reducing mortality from breast cancer, and data from several other studies also support a benefit to women 40-49. But, the problem seems to be that thus far there has been no single randomized-controlled trial which has showed statistically-significant proof of benefit from mammography screening for women ages 40-49. Dr. Van Hook further stated that much more is at stake here than just dollars spent to save lives and that the decisions regarding health care intervention which affects our society should perhaps, involve not only science, but should also take into account the willingness of those most affected by those decisions. To accept some degree of uncertainty, especially when there is controversy or less than scientific proof of benefit. Dr. Van Hook concluded by saying that the beneficiaries of breast cancer screening, those who stand to gain or lose the most from it, our mothers, wives, and daughters are willing to do just that.

The Committee then turned to Lois A. Anderson, Co-Facilitator and Founder of A surviving Breast Cancer Support group and Co-Captain of York County Pennsylvania Breast Cancer Coalition. Ms. Anderson expressed her outrage by the NIH Consensus Conference's decision on mammography screening for women 40 to 49.

Ms. Anderson described her own experience with breast cancer. She was diagnosed when she was 40 years old. Her mammogram failed to detect the disease and after some suspicious bruising, Ms. Anderson found a lump while doing a self breast exam. A mastectomy was performed one month later and 5 of 11 lymph nodes were found to be cancerous. These findings made her a stage III breast cancer patient with less than a 40 percent chance of surviving 5 years.

Ms. Anderson said that the incidence of breast cancer in younger women is increasing and the NIHs decision to NOT recommend mammograms for women below 50 years of age will certainly cause an increase in the death rate from breast cancer.

Ms. Anderson presented the Subcommittee with letters from over 226 women under the age of 50 who have been diagnosed with Breast cancer through the use of a mammogram.

Ms. Anderson told the Committee that while breast cancer is not perfect, it is the best tool we have for detecting breast cancer early and that deadly confusion over screening mammography will result from the NIH's decision if these guidelines are not changed.

Next the Subcommittee heard from Ms. Lorene Knight, a volunteer with the American Cancer Society and a member of the

Pennsylvania Breast Cancer Coalition. Ms. Knight is a 54 year old African American woman, and a 7-year breast cancer survivor. Ms. Knight told the Subcommittee that her first mammogram was performed at the age of 36 because of the presence of fibrocystic tissue and a family history of breast cancer. Her sister lost her life to the disease at the age of 43 and her mother is a 5 year breast cancer survivor.

Ms. Knight stated that she was most disturbed by the findings of the NIH Consensus Development Conference statement and felt that their statement would lure entirely too many women of all races, and in their 40s, into a false sense of security about the odds that breast cancer will not likely happen to them during this decade of their lives.

Citing recent statistics from 4 hospitals in Lancaster County, Ms. Knight stated that one hospital, during the 95-96 fiscal year, 105 women underwent breast cancer surgery and nearly 36% of them were under the age of 50. At a second hospital, 21 women underwent breast cancer surgery and 8 of the 21 women were under the age of 50. She also told the Subcommittee that as a volunteer with the American Cancer Society's Reach to Recovery program, she has yet to visit one recovering breast cancer patient that is African American. She believes that this is because not enough African American women are having early detection procedures. The breast cancer mortality rate for African American women increased by 2.6% at a time when the mortality rate in white women declined by 5.5%.

Ms. Knight concluded that every woman, of every race, in every community should have access to mammography at age 40 if that is what she determines to be necessary for her, dictated by family history, her physician and her personal health factors.

Our last witness of the day was Representative Katie True, who represents the 37th legislative district in Pennsylvania. Ms. True told the Subcommittee that one of the weapons that she has chosen to fight breast cancer is House Bill 134. This bill which has already passed the House, would provide for a state income tax checkoff for breast cancer research. The donation is deducted from the tax refund and does not constitute a change against the income tax revenue's to the State.

Representative True also stated that the second weapon used to battle breast cancer is education. She stated that self breast exams combined with mammograms can save many lives. Women still hesitate to look after themselves first, usually putting others needs before their own.

Representative True concluded that the recommendation of the NIH Consensus Development Conference on Breast Cancer Screening is irresponsible, and she questioned the motives behind such a recommendation—plain and simple—their message is wrong and deadly.

MARCH 4, 1997—WASHINGTON, DC

On March 4, 1997, Secretary of Health and Human Services Donna Shalala appeared before the Subcommittee on Labor, Health and Human Services and Education to discuss the fiscal year 1998 budget.

At that hearing, I took the opportunity to discuss the NIH Consensus Development Conference recommendations with the Secretary and asked her to take immediate steps towards encouraging women ages 40-49 to undergo mammogram screening. I told the Secretary that the panel finding that mammograms were not warranted for women in the age bracket 40 to 49 has caused quite a stir. And that my own view is that the evidence is substantial, if not overwhelming, that mammograms are very helpful for women of this

age group, they do save lives, and that there ought to be a prompt conclusion by HHS to that effect. When there is a public determination that mammograms are not warranted for women 40-49, many women are reading that to mean that a mammogram is not necessary. I also told the Secretary that I felt that there is not a sufficient sense of urgency in the approach that the Department is taking with regard to this issue in allowing another 60 days to pass before a final judgment is made on this issue. I further stated that when it's a matter of dollars and cents, and there is no clear scientific evidence to the contrary, I think the word ought to come from the Secretary of Health and Human Services that, notwithstanding the cost, we're going to make sure that mammograms are made available to women ages 40-49.

Mr. ROTH addressed the Chair.

The PRESIDING OFFICER. The Senator from Delaware is recognized.

Mr. ROTH. Mr. President, I thank my distinguished friend, Senator DOMENICI, for allowing me to go next. I will limit my remarks to 5 minutes.

(The remarks of Mr. ROTH pertaining to the introduction of S. 436 are located in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

The PRESIDING OFFICER. The Senator from New Mexico is recognized.

Mr. DOMENICI. I thank the Chair.

I was pleased to accommodate the distinguished chairman of the Finance Committee.

(The remarks of Mr. DOMENICI pertaining to the introduction of S. 437 are located in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

The PRESIDING OFFICER. The Senator from New Jersey.

Mr. LAUTENBERG. Madam President, I ask unanimous consent I be yielded 10 minutes from the time that is allocated to the Democratic side here, under the auspices of Senator BINGAMAN.

The PRESIDING OFFICER. Without objection, it is so ordered.

THE BUDGET

Mr. LAUTENBERG. Madam President, one of the subjects that dominates the landscape these days, of course, is the budget. How we are going to function as a society, what are the priorities, how will we finance these priorities and at the same time reach an objective that all of us care about, and of course that is getting a balanced budget by the year 2002. Of course, that is getting a balanced budget by the year 2002.

The President has presented a budget to achieve that objective. There are disputes about how we reach that objective, where do we cut further, what is the revenue stream. I, therefore, Madam President, use this opportunity to comment on what I see as the lack of a budget proposal from the Republican side, from the majority side.

The President has put down a budget. We have talked about it in the Budget Committee. I am the ranking Demo-

crat on the Budget Committee. We have had numerous hearings as we explored various avenues, various parts of the equation with proponents and some opponents trying to dissuade us from proceeding with the President's budget.

On the other hand, we have not seen anything yet from the Republican side, the majority side, I point out, Madam President. They have produced one piece of budget legislation this year, but it is not a balanced budget. It is the notion that we ought to be giving a big tax break, primarily devoted to the wealthy in our country. The Republican tax break will blow a huge hole in the deficit, even as we struggle to get down to a zero budget deficit by the year 2002.

In the first 5 years, the Republican plan would cost \$200 billion. In the next 5 years, these costs would increase 60 percent to \$325 billion for a total of \$526 billion over the 10-year period. This chart will help explain exactly where it is we are going.

It causes a ballooning of the deficit. We see it from 1997, which is on the chart projected at \$120 billion and expected to be less by the time we reach the end of the fiscal year, September 30. It continues to expand. In the year 2002, when we are striving to have a zero budget deficit, we are at \$239 billion, unless some way is found to pay for these tax breaks. They are not free. If we adopt the Republican tax scheme, we would have to make deeper cuts someplace. I guess that would have to come from Medicare, Medicaid, education, transportation, crimefighting, and environmental protection.

These tax breaks are also backloaded. Their costs explode, as we can see by the expansion of the deficit, after the year 2002. And, believe it or not, these tax breaks are bigger than those that were originally in the Contract With America, larger than the tax breaks that were proposed last year.

This chart is from the Joint Committee on Taxation. It is now at \$200 billion, expanded to \$525 billion. These are the tax cuts as planned, to \$525 billion. That would be a terrible consequence. That is in the year 2007.

Finally, the Republican tax breaks are overwhelmingly tilted toward the very wealthy. According to one analysis, on average, the Republican tax scheme would give a tax break each year of \$21,000 for those who make \$645,000 a year, the top 1 percent of the income earners in our country. But if you are in the middle 20 percent of our wage earners and you make \$27,000 a year, you would get \$186 worth of tax relief, 50 cents a day—50 cents a day—for the average hard-working family.

It borders on insulting to suggest that someone who makes \$645,000 is entitled to a tax break of \$21,000—I hardly think that those people need any help—and if you make \$27,000, which is the per capita income of the middle 20